Advisory Commission on Childhood Vaccines (ACCV) update

(June to August 2022)

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Priorix

<u>3 June 2022</u> - Approval of Priorix for the prevention of measles, mumps, and rubella in individuals 12 months of age and older.

Vaxneuvance

17 June 2022 - Vaxneuvance for the prevention of invasive disease caused by *Streptococcus* pneumoniae serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F, and 33F in individuals 6 weeks through 17 years of age.

Moderna and Pfizer-BioNTech COVID-19 Vaccines

17 June 2022 - Emergency use of the Moderna COVID-19 Vaccine and the Pfizer-BioNTech COVID-19 Vaccine for the prevention of COVID-19 to include use in children down to 6 months of age.

Influenza Vaccines

July 2022 - Approved the influenza vaccines for the 2022-2023 influenza season (eight vaccines).

Comirnaty

8 July 2022 - Approval of Comirnaty for individuals 12 through 15 years of age for the prevention of COVID-19 caused by SARS-CoV-2.

Novavax COVID-19 Vaccine

13 July 2022 - Emergency use authorization for Novavax COVID-19 Vaccine, Adjuvanted for the prevention of COVID-19 caused by SARS-CoV-2 in individuals 18 years of age and older.

JYNNEOS

9 August 2022 - Emergency use authorization of JYNNEOS vaccine to allow healthcare providers to use the vaccine by intradermal injection for individuals 18 years of age and older who are determined to be at high risk for monkeypox infection. The EUA also allows for use of the vaccine in individuals younger than 18 years of age determined to be at high risk of monkeypox infection; in these individuals JYNNEOS is administered by subcutaneous injection.

Novavax COVID-19 Vaccine

19 August 2022 - Emergency use authorization of of Novavax COVID-19 Vaccine, Adjuvanted for the prevention of Coronavirus Disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 12 through 17 years of age. The agency previously authorized the vaccine for individuals 18 years and older.

Moderna and Pfizer-BioNTech COVID-19 Vaccines

31 August 2022 — Amended the EUAs of the Moderna COVID-19 Vaccine and the Pfizer-BioNTech COVID-19 Vaccine to authorize bivalent formulations of the vaccines for use as a single booster dose at least two months following primary or booster vaccination. The bivalent vaccines, which we will also refer to as "updated boosters," contain two messenger RNA (mRNA) components of SARS-CoV-2 virus, one of the original strain of SARS-CoV-2 and the other one in common between the BA.4 and BA.5 lineages of the omicron variant of SARS-CoV-2.

The Moderna COVID-19 Vaccine, Bivalent, is authorized for use as a single booster dose in individuals 18 years of age and older. The Pfizer-BioNTech COVID-19 Vaccine, Bivalent, is authorized for use as a single booster dose in individuals 12 years of age and older.

FDA COVID-19 Website

FDA has a website dedicated to its COVID-19 activities, including FDA's pandemic response activities pertaining to vaccines, testing, therapeutics, and devices. The website is frequently updated and is a resource for the public, including healthcare providers and industry. https://www.fda.gov/emergency-preparedness-and-response/counterterrorism-and-emerging-threats/coronavirus-disease-2019-covid-19

Thank you!